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## **OLR Bill Analysis**

### **sHB 5042**

#### ***AN ACT CONCERNING THE REGENERATIVE MEDICINE RESEARCH FUND.***

#### **SUMMARY:**

This bill:

1. broadens the scope of the existing Stem Cell Research Fund to include regenerative medicine;
2. changes the fund's name to the Regenerative Medicine Fund to reflect this new scope;
3. makes corresponding changes to the names and composition of the advisory committee that reviews and approves grants from the fund;
4. adds the Connecticut Innovations, Inc. (CII) chief executive officer (CEO) to the renamed Regenerative Medicine Advisory Committee and designates her the committee's chairperson, replacing the Department of Public Health (DPH) commissioner, who remains on the committee;
5. extends the time for making grants by five years, from 2015 to 2020; and
6. requires the advisory committee to prepare a strategic plan for reviewing peer review committee recommendations about grant applications, awarding grants, and measuring grant recipients' performance.

The bill also makes many technical changes conforming to the fund's new scope and modified administrative structure.

The bill requires the Bioscience Advisory Committee's 13 members

to adhere to the Code of Ethics for public officials. The committee oversees the Connecticut Bioscience Innovation Fund, which finances projects to improve the health care delivery system, lower health care costs, and create bioscience jobs. CII manages the fund and, under current law, may tap it to cover the administrative cost of providing this service. The bill eliminates this authority, requiring CII to absorb these costs with its own funds (§§ 6-8).

EFFECTIVE DATE: October 1, 2014

## **§§ 2 & 9 — RENENERATIVE MEDICINE RESEARCH FUND**

The bill renames the Stem Cell Research Fund the Regenerative Medicine Research Fund, reflecting its broader scope encompassing stem cell and regenerative medicine research. The latter encompasses research into the process for creating living, functional tissue to repair or replace tissues or organ functions lost due to aging, disease, damage, or congenital defects. Regenerative medicine includes stem cell research, which the law does not define.

The bill shifts the administrative responsibility for of awarding grants from the DPH commissioner to CII's CEO. CII is the state's quasi-public economic development agency that, among other things, invests venture capital in new and established businesses developing new technologies. The bill also authorizes CII to enter into agreements with various other entities that allow grant recipients to collaborate with other researchers on advance research.

## **§ 2 — RENENERATIVE MEDICINE RESEARCH ADVISORY COMMITTEE**

### ***Purpose***

The bill renames the Stem Cell Research Advisory Committee the Regenerative Medicine Advisory Committee. The committee's current stem cell-related duties include developing grant applications and requiring eligible institutions seeking research grants to describe themselves, their plans for stem cell research, and the possible financial benefits to the state resulting from their research.

The bill requires the renamed committee to perform these duties with respect to regenerative medicine research. It also requires the committee to direct CII's CEO, instead of the DPH commissioner, on awarding grants, which it must do after considering the peer review committee's recommendations.

***Composition***

The bill retains the structure of the current 18-member committee, but changes the members' qualification to reflect the inclusion of regenerative medicine research. The bill keeps the DPH commissioner on the committee but removes her as chairperson. It adds CII's CEO (or her designee) to the renamed committee, increasing its membership to 19, and making the CEO or her designee the board's chairperson.

The bill keeps the current appointing authorities, but changes the qualifications of the members they must appoint to reflect the inclusion of regenerative medicine research.

1. The governor continues to appoint four members, but two must have background and experience in embryonic stem cell or regenerative medicine research and two must have background and experience in business, law, or ethics.
2. The Senate president pro tempore and the House speaker each continue to appoint two members, but they must have background and experience in private-sector regenerative medicine research and development (R&D) instead of embryonic stem cell R&D.
3. The House and Senate majority leaders each continue to appoint two members, but they must be academic researchers specializing in regenerative medicine, instead of stem cell, research.
4. The Senate and House minority leaders continue to appoint two members, but (1) the former must appoint someone with background and experience in public- or private-sector regenerative medicine, instead of stem cell, research and

development and (2) the latter must continue to appoint someone with a business or financial investment background and experience.

The bill makes conforming technical changes to the board's makeup, member terms, and operations, including the requirement prohibiting a member from reviewing or considering a grant application in which he or she has a financial stake.

### ***Duties***

The bill realigns the board's duties to encompass regenerative medicine research and adds a new one. It requires the committee to prepare a comprehensive strategic plan, including awarding grants. At a minimum, the plan must identify methods or strategies to achieve the fund's economic development objectives, build capacity for innovation, and sustain the money invested in the fund.

The bill also requires the committee to work with CII, instead of the DPH commissioner, to develop a program that encourages the development of nonappropriated state funds and promotes regenerative medicine, among other things.

### ***CII Support***

Under the bill, CII provides administrative support to the fund, which includes helping the committee (1) develop and review grant applications and (2) prepare and execute funding agreements. But, under the bill, CII must also help the committee evaluate the grant-funded research's economic impact.

Specifically, CII must help the committee develop performance measures and data collection systems. The data must include each recipient's employment statistics; its business accomplishments and outcomes; peer-reviewed articles and published papers; partnerships and collaborations with other entities; licenses, patents, and invention disclosures; intellectual property developed with the grant that was put to commercial use; and research funds from other sources.

**§ 4 — REGENERATIVE MEDICINE RESEARCH PEER REVIEW COMMITTEE*****Purpose***

The bill renames the Stem Cell Research Peer Review Committee the Regenerative Medicine Research Peer Review Committee, changing its composition and purpose to reflect the inclusion of regenerative medicine research.

***Composition***

The bill changes the qualifications and appointing authority of the committee members, also reflecting its emphasis on regenerative medicine research. It ends the DPH's commissioner authority to appoint people to the five-member committee after September 30, 2014. Until that date, the commissioner must fill any vacancies by appointing members with a background and knowledge related to regenerative medicine research, instead of stem cell research.

The law's current requirements regarding attendance, ethics, and conflicts of interest apply to these members. As under current law, these DPH-appointed members serve four-year terms. But they cannot serve consecutive four-year terms nor concurrently serve on the Regenerative Medicine Advisory Committee.

The DPH-appointed members may continue serving on the committee until their terms expire. However, on October 1, 2014, appointing power shifts to the CII CEO and her appointees must meet the bill's requirements for background and knowledge related to regenerative medicine. The CII appointees serve four-year terms, except for the first three, who serve two-year terms. Like the DPH appointees, these appointees cannot serve consecutive four-year terms nor concurrently serve on the Regenerative Medicine Advisory Committee. The law's current requirements regarding attendance, ethics, and conflicts of interest apply to them.

***Duties***

Under current law, before the advisory committee awards grants, the peer review committee considers grant applications and makes

recommendations to the DPH commissioner and the advisory committee about their ethical and scientific merit. Under the bill, the peer review committee must make recommendations to CII with respect to regenerative medicine research.

The bill does not extend to the reconstituted committee the requirement that its members make themselves aware of the National Academies Guidelines for Human Embryonic Stem Cell Research and make recommendations to the advisory committee and the DPH commissioner about adopting any or all of these guidelines in regulations.

### ***Compensation***

The bill changes the funding source for compensating committee members for their reviews. Under current law, the funds come from the Stem Cell Research Fund, and the compensation rate is determined by the DPH commissioner, in consultation with the Department of Administrative Services and the Office of Policy and Management. Under the bill, CII compensates the members with its funds at a rate its board of directors sets.

### **COMMITTEE ACTION**

Commerce Committee

Joint Favorable Substitute

Yea 17 Nay 0 (03/20/2014)